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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,784	04/02/2004	Paul J. Thompson	E001/7067US1	9955

21127 7590 08/27/2009
RISSMAN HENDRICKS & OLIVERIO, LLP
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BOSTON, MA 02114

EXAMINER

GANESAN, SUBA

ART UNIT	PAPER NUMBER
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3774

NOTIFICATION DATE	DELIVERY MODE
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08/27/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/816,784	Applicant(s) THOMPSON ET AL.	
	Examiner SUBA GANESAN	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-10,12-22,24 and 26-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-10,12-22,24 and 26-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 6/12/2009 have been fully considered but they are not persuasive.
2. Examiner acknowledges the claim amendments dated 6/12/2009, and notes that the claim amendments further define the location of the bending notches, as well as clarify the term "radial" with respect to the position of the notches. Because of these amendments, the rejection of claim 24 under 35 USC 102(b) has been withdrawn, and all of the remaining claim rejections under 35 USC 103(a) have been updated to address the location of bending and bending notches. Note that the same references have been used to address the claim amendments.
3. Applicant argues that Phelps lacks predefined bend locations. This is not persuasive. The bend location is at the end of the strut, it is considered "pre-defined" because the bend can occur along the length of the end of the stent, but not along the mid-portion of the stent. Thus, to some degree, the bend location is "pre-defined". The claim does not require the location be specified with any more precision.
4. Applicant argues that Phelps in view of Shanley lacks a reduced cross section in the radial direction. Examiner disagrees. Shanley teaches notching of a stent strut in the direction of bending (see fig. 8, and abstract); In order for the hinges of Shanley to work, they are notched in the direction of deformation, which happens to be circumferential. In the case of Phelps, the direction of deformation is radial, with the flared end struts deforming at a predefined bend location (at the end of the stent). One of ordinary skill in

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the art would understand that in combining the stent of Phelps with the bending notches of Shanley, the location of the bending notches would be modified to yield a radial bend. Such a modification would have occurred using known methods and yielding predictable results. One of ordinary skill would be motivated to provide such a modification in order to provide low expansion force requirements for the radially flared end portion of the Phelps stent. Likewise, in combining Bonsignore with Shanley, the location of the bending notches would be modified to yield a radial bend.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims **1, 3, 5-10, 12-17, 24, 26, 28-31** are rejected under 35 U.S.C. 103(a) as being unpatentable over Phelps et al. (U.S. Pat. No. 6,290,728) in view of Shanley (U.S. Pat. No. 6,241,762).

2. Phelps et al. discloses a stent comprising a main body defining a longitudinal axis and a radial direction, and with a plurality of cells and flared ends with predefined bend locations. The end structure can be considered struts coupled to the ends of the main body. The end structure includes a plurality of cantilever members connected at the bend location (see for example fig. 8). Phelps further discloses a stent implanted at the junction between two vessels, with the main body located within the first vessel

lumen and the end structure conformed to an interior surface of the second vessel lumen (fig. 8). The stent of Phelps is delivered via a delivery catheter (146).

3. However, Phelps does not disclose the use of notches to facilitate bending. Shanley teaches the use of notches for the purpose of bending sections of a sent. These notch sections have a reduced cross sectional area (see fig. 8 and Abstract) which appear to be 25-60% smaller than adjacent locations (see hinge 90, fig. 4b), and are located on both the interior and exterior surfaces of the stent (see fig. 3a, 4b). Shanley further teaches the use of shoulders at the bend locations (see fig 4b, noting that notch sides 96 define shoulders of struts 88) and linking members that extend between the struts (see fig. 10 noting that a linking member connects adjacent struts 72 via notches 74).

4. Shanley teaches reducing the cross-sectional area of the cantilever member in the direction of bending (see fig. 8, for example), such that the reduced profile facilitates the bending (see abstract). In Shanley, the bending occurs circumferentially along the stent body; in Phelps, the bending occurs radially, at the flared end of the stent. Examiner considers it obvious to one of ordinary skill in the art to provide notches as taught by Shanley to facilitate bending of the Phelps end struts. In making such a modification, one would place the notches radially relative to the rest of the stent, because the end struts of Phelps are radially bending. Such a modification would have occurred using known methods and yielding predictable results. One of ordinary skill would be motivated to provide such a modification in order to provide low expansion force requirements for the radially flared end portion of the Phelps stent.

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5. Therefore it would have been obvious to one of ordinary skill in the art to modify the bend locations of Phelps to include notches, shoulders, and linking members as taught by Shanley for the purpose of facilitating improved bending and reducing strain at the bend location to eliminate the risk of breaking. Although the notches of Shanley appear to be about 25-60% smaller than adjacent sections, Shanley does not specifically disclose this. However, it would have been obvious to one of ordinary skill in the art to include a reduced cross sectional area that is 25-60% smaller than adjacent locations for the purpose of defining a specific bend limit (col. 9 line 6-17).

6. It is noted that such a modification of Phelps would have been within the level of ordinary skill in the art, since living hinges are common means of bending components relative to one another. The combination of Phelps and Shanley would have yielded predictable results (specific bending locations) and would have occurred using known methods.

7. Claims **18-22, 27, 32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonsignore et al. (U.S. P.G. Pub. No.: 2004/0186555) in view of Shanley (U.S. Pat. No. 6,241,762).

8. Bonsignore et al discloses a stent comprising a main body with a plurality of cells and flared ends with predefined bend locations (see fig. 7). X-ray visible marker 804 is positioned within enlargement 802 of the flared cantilever member. Bonsignore et al. discloses a stent with support members defining an undulating pattern of peaks and

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valleys extending about a circumference with end struts flared relative to the main body, the end struts being connected to at least one of the peaks of the main body (see fig. 7). Bonsignore does not disclose the use of notches to facilitate bending. Shanley teaches the use of notches for the purpose of bending sections of a stent.

9. Shanley teaches reducing the cross-sectional area of the cantilever member in the direction of bending (see fig. 8, for example), such that the reduced profile facilitates the bending (see abstract). In Shanley, the bending occurs circumferentially along the stent body; in Bonsignore, the bending occurs radially, at the flared end of the stent. Examiner considers it obvious to one of ordinary skill in the art to provide notches as taught by Shanley to facilitate bending of the Bonsignore end struts. In making such a modification, one would place the notches radially relative to the rest of the stent, because the end struts of Bonsignore are bending radially. Such a modification would have occurred using known methods and yielding predictable results. One of ordinary skill would be motivated to provide such a modification in order to provide low expansion force requirements for the radially flared end portion of the Bonsignore stent.

Therefore it would have been obvious to one of ordinary skill in the art to modify the bend locations of Bonsignore to include notches, shoulders, and linking members as taught by Shanley for the purpose of facilitating improved bending and reducing strain at the bend location to eliminate the risk of breaking.

10. It is noted that such a modification of Bonsignore would have been within the level of ordinary skill in the art, since living hinges are common means of bending components relative to one another. The combination of Bonsignore and Shanley would

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have yielded predictable results (specific bending locations) and would have occurred using known methods.

11. Regarding claims 20,21, Bonsignore fails to disclose end struts connected to every peak or every third peak. It would have further been obvious to one of ordinary skill in the art to modify the stent of Bonsignore to include connecting an end strut to every peak or every third peak of the end support member for the purpose of increasing the amount of anchoring and support structures at the implantation site and/or modifying the flexibility of the entire stent body.

12. With respect to claim 22, Bonsignore fails to disclose end struts with two enlargements with radiopaque markers for each end strut. It would have been further obvious to one of ordinary skill in the art to modify the stent of Bonsignore to include two enlargements including radiopaque markers for the purpose of increasing the visibility of the stent about its entire circumference.

13. With respect to claim 33, it would have been obvious to have flared end struts connected to all of the peaks at one end of the main body for the purpose of increasing the radiopacity of that end of the stent. Such a modification of Bonsignore would have occurred using known methods and yielding predictable results to one of ordinary skill in the art.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./

Examiner, Art Unit 3774

/William H. Matthews/

Primary Examiner, Art Unit 3774